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19 UNITED STATES DISTRICT COURT

20 CENTRAL DISTRICT OF CALIFORNIA

21 In Re: NEXIUM

22 (ESOMEPRAZOLE) PRODUCTS

23 LIABILITY LITIGATION

24 This document relates to:

25 ALL CASES

Case No.: 12-ml-2404 DSF (SSx)

**DEFENDANTS' REPLY IN  
FURTHER SUPPORT OF MOTION  
TO EXCLUDE PLAINTIFFS'  
GENERAL CAUSATION EXPERT  
B. SONNY BAL, M.D., J.D., M.B.A.**

Judge: Hon. Dale S. Fischer  
Courtroom: 840 - Roybal

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28 **DEFENDANTS' REPLY IN FURTHER SUPPORT OF MOTION TO  
EXCLUDE PLAINTIFFS' GENERAL CAUSATION EXPERT B. SONNY  
BAL, M.D., J.D., M.B.A.  
Case No. 12-ml-2404 DSF (SSx)**

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1 *randomized, crossover, controlled clinical trial*, J. BONE MINER. RES.  
2 2010; 25 (10): 2205-11 .....6

3  
4 **EXHIBITS**

5 Exhibit A: Excerpts from Transcript, Feb. 19, 2014 *Nexium*® Dep. Dr. Bal  
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## I. INTRODUCTION

The central argument in Plaintiffs' Memorandum of Points and Authorities in Opposition to Defendants' Motion to Exclude Plaintiffs' General Causation Expert B. Sonny Bal, M.D., J.D., M.B.A. (Master Dkt. 287) (hereinafter "Response") is that their expert Dr. Bal's opinions may be shaky and not peer reviewed, but the proper recourse for this Court is to allow the jury to decide what weight to give his testimony, rather than exclude it altogether. *Daubert* and the cases interpreting it, including the Ninth Circuit's recent *en banc* opinion in *Estate of Barabin v. AstenJohnson, Inc.*, 740 F.3d 457, 463-64 (9th Cir. 2014), make clear that the district court is obligated to evaluate and exclude unreliable, irrelevant expert testimony through its gatekeeping function.

A trial court's "gatekeeping" obligation to admit only expert testimony that is both reliable and relevant is especially important "considering the aura of authority experts often exude, which can lead juries to give more weight to their testimony."

*Stanley v. Novartis Pharm. Corp.*, No. 11-cv-03191, 2014 WL 1316217, \*3 (C.D. Cal. Apr. 2, 2014) (quoting *Mukhtar v. Cal. State Univ.*, 299 F.3d 1053, 1063-64 (9th Cir. 2002)). It is improper to simply turn such unreliable evidence over to the jury to weigh.

Accordingly, the Court should answer all three questions presented in Section III of Defendants' opening brief in the negative:

1. Dr. Bal is unqualified to opine that Nexium® can cause osteoporosis, osteopenia and osteoporotic fractures (collectively "OP")<sup>1</sup>;

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<sup>1</sup> Plaintiffs assert as a fact that several studies have been published which link PPI use and OP. (Resp. at pp. 2-3; nn.2-4; pp. 13-14.) As discussed in Defendants' Motion to Strike filed contemporaneously herewith (Master Dkt. 312), Plaintiffs' reference to

2. Dr. Bal's opinion that Nexium® is merely "associated" with OP is not "helpful" when the issue is causation; and,
3. Dr. Bal's opinion is not reliable because it is litigation-driven and there is too great an analytical gap between the data he relies upon and his conclusions.

## II. ARGUMENT

### A. Plaintiffs' Response Does Not Demonstrate That Dr. Bal Is Qualified To Opine About Whether Nexium Can Cause OP.

Dr. Bal<sup>2</sup> is an orthopedic surgeon who specializes in the repair and replacement of cartilage, not bone. **Exh. A** (Bal Dep. 7:6-13.) To the extent that he deals with bones, his practice consists of surgically repairing them. (*Id.* at 108:10-15.) While AstraZeneca does not dispute that he may have "exceptional familiarity and expertise with . . . bone," this expertise has nothing to do with calcium absorption in the gastrointestinal tract or whether treatment with Nexium can inhibit this absorption so as to lead to reduced bone mineral density and OP. Dr. Bal professes no particular expertise in this core issue. Noticeably absent in Plaintiffs' Response regarding his qualifications (Resp. at p. 4, l. 20 – p. 5, l. 6, p. 8, ll. 12-15), are citations to Dr. Bal's own testimony or his CV. That comes as no surprise; Dr. Bal testified that: "When people come to us with a broken leg, they

studies their expert never reviewed or relied upon is improper. Regardless, these studies do not establish causation as a "fact." Defendants' expert authored one of the studies and opines that there is insufficient evidence to conclude that PPIs play a causal role in OP. (Master Dkt. 255-4, Targownik Rpt., p. 9.)

<sup>2</sup> The cited portions of Dr. Bal's February 19, 2014 deposition transcript in this matter ("Bal Dep.") are attached as **Exhibit A** to the Declaration of Katherine A. Winchester in Support of Defendants' Reply in Further Support of Motion to Exclude Plaintiffs' General Causation Expert B. Sonny Bal, M.D., J.D., M.B.A.

1 come to us not to review literature but to fix the broken leg." **Exh. A** (Bal Dep.  
2 108:13-15.)

3 Plaintiffs sole support for Dr. Bal's qualifications is that (1) he is an  
4 orthopedic surgeon who has operated on patients some of whom have OP and (2)  
5 he has read some medical literature discussing the relationship between PPI's and  
6 OP. On this basis alone, they assert that he is "exceptionally" qualified to testify as  
7 to whether treatment with Nexium can cause OP. They also argue that Dr. Bal's  
8 simultaneous involvement in the *Fosamax* litigation in which he expressed  
9 scientific positions that contradict his core opinion in this case should not taint his  
10 qualifications here. Neither argument should persuade this Court to find Dr. Bal  
11 qualified on the issue at hand – whether Nexium® can **cause** OP.

12 Moreover, the fact – standing alone – that Dr. Bal is a medical doctor does  
13 not qualify him to testify here. As discussed in Defendants' opening brief, the  
14 question is whether the testimony falls within the expert's area of **relevant**  
15 **experience**. (See Master Dkt. 255, p. 13 and cases cited therein.) Because Dr. Bal  
16 is not opining on surgical technique or even whether surgery is needed, he is not  
17 qualified because his experience is not relevant. Dr. Bal bases his opinion on his  
18 reading of epidemiologic scientific literature and their posited mechanisms of  
19 action relating to calcium homeostasis. His clinical work as a surgeon does not  
20 lend any particular expertise to reliably undertake this expert analysis and reach a  
21 relevant, reliable opinion based upon them. *Mascarenas v. Miles, Inc.*, 986 F.  
22 Supp. 582, 593 (W.D. Mo. 1997) (cancer surgeon not an expert in cancer  
23 causation).

24 Plaintiffs' cited cases do not provide to the contrary. First, neither *Stanley*  
25 nor *Tucker* address the issue. In *Stanley*, the plaintiff was a cancer patient who  
26 claimed that her osteonecrosis was caused by bisphosphonate use. 2014 WL

1 1316217 at \*8. Her expert dentist was a specialist in osteonecrosis in cancer  
 2 patients, had published on osteonecrosis caused by bisphosphonates and had  
 3 reviewed all of her medical and dental records and the depositions of all of the  
 4 treating physicians. *Id.* In *Tucker v. SmithKline Beecham Corp.*, the doctor  
 5 expert's credentials were "undisputed." 701 F. Supp. 2d 1040, 1047 (S.D. Ind.  
 6 2010). Regardless, the expert psychiatrist, who testified about whether treatment  
 7 with an anti-depressant can increase the risk of suicide, was also a  
 8 neuropsychopharmacologist (specialist in how the brain reacts to medicine) and he  
 9 had "written many peer-reviewed medical journal articles concerning the SSRI  
 10 class of drugs, including [the drug at issue], and the risks and benefits of those  
 11 drugs." *Id.* Dr. Bal, having never studied or published on PPIs generally or  
 12 Nexium® specifically, is not in the same position. And, he professes no specialty  
 13 in how medicine impacts any part of the body.

14 Finally, *In re Avandia*, is distinguishable for two reasons. First, the court  
 15 noted that the movant "did not elaborate on the challenge" that as a cardiologist the  
 16 expert was not particularly qualified to analyze and draw conclusions from  
 17 epidemiologic research. No. 07-md-01871, 2011 WL 13576, \*10 (E.D. Pa. Jan. 4,  
 18 2011). Second, the court recognized that the doctor was a professor and researcher  
 19 specializing in "lipoprotein metabolism" including "apoB as a marker for vascular  
 20 disease" – the precise issue in the litigation. *Id.* The same does not hold true here.

21 Next, Plaintiffs argue that it would be "prejudicial" to hold Dr. Bal's very  
 22 recent testimony in the *Fosamax* litigation against him. (Resp. at p. 10, l. 28.) The  
 23 *Fosamax* deposition took place 1 month **before** his deposition here and less than  
 24 two months **after** he submitted his Rule 26(A) Report in this case. As such, his  
 25 testimony in *Fosamax* came during the height of his duties in this litigation. When  
 26 deposed in *Fosamax*, (at best) he forgot the opinions expressed in his *Nexium*

1 expert report. When deposed in *Nexium*, Dr. Bal could recall little about his prior  
2 testimony. Notably, the deposition testimony AstraZeneca cites here, was not  
3 focused on "a particular Fosamax plaintiff" or other case-specific details. The  
4 testimony instead involved the **science** underlying his fracture opinion in *Fosamax*  
5 as it relates to the science underlying his opinion here. Dr. Bal was unable or  
6 unwilling to discuss those issues.

7 It is axiomatic that one cannot be deemed an "expert" if his recall of the  
8 relevant subject matter is that limited. In *Fosamax*, he was defending a  
9 pharmaceutical manufacturer. Here he is on the other side. Accordingly, Dr. Bal's  
10 inability to recall core concepts from one month to the next shows either that the  
11 issues discussed in the deposition are not those he addresses in his ordinary clinical  
12 practice or his testimony is influenced by litigation. Either results in his exclusion.

13 Moreover, Dr. Bal alleges that Nexium® "may exert a direct action on  
14 skeletal cells called osteoclasts . . . leading to altered bone turnover." (Resp. at p.  
15 15, ll. 1-4.) This is precisely how bisphosphonates like Fosamax® work.  
16 Bisphosphonates slow or stop osteoclasts from resorbing bone and releasing  
17 calcium. (See, e.g., *id.* at pp. 9-10.) In *Fosamax*, Dr. Bal says a direct action on  
18 osteoclasts cannot cause fracture. Here he says it does.

19 **B. Plaintiffs' Response Highlights The Lack of Known Mechanism of**  
20 **Action.**

21 Dr. Bal has not identified **any** scientific basis for his opinion that Nexium®  
22 **use** "leads to poor calcium intake." (*Id.* at p. 9.) Yet, he opines that this is the  
23 plausible mechanism by which Nexium® causes the types of injuries alleged by  
24 Plaintiffs here. In fact, he never even tried to research the proposition. **Exh. A**  
25 (Bal Dep. 133:5-9.)  
26

1 If he had, he might have located (as Defendants' experts did) the  
 2 independent clinical studies *Hansen 2010*<sup>3</sup> and *Wright 2010*<sup>4</sup> which both found  
 3 that acid suppressors (including Nexium®) do not reduce calcium absorption.  
 4 (Master Dkt. 255-4, Targownik Rpt. at p. 7) ("multiple recent studies evaluating  
 5 calcium absorption [and PPI use] have not shown any deleterious effect on calcium  
 6 absorption, except when evaluating solely the absorption of calcium carbonate in  
 7 the non-fed state."); (Master Dkt. 256-5, Bikle Rpt. at p. 16) ("inhibiting calcium  
 8 absorption by blocking gastric acid secretion and thus reducing the solubilization  
 9 of calcium salts, has not been shown to reduce intestinal calcium absorption when  
 10 put to the test in humans").<sup>5</sup> Dr. Bal was unfamiliar with these studies. **Exh. A**  
 11 (Bal Dep. 139:2-14.) Rather, he admitted at his deposition that *Ensrud*<sup>6</sup> (the only  
 12 calcium absorption study he reviewed) did not study acid suppressing medication  
 13 at all. (*Id.* at 136:1-11.) Rather, it simply found that women with low calcium  
 14 intake and absorption rates have more hip fractures. (*Id.*) It did not study **why**  
 15 those women had low calcium absorption. (*Id.*)

16  
 17 <sup>3</sup> Hansen K.E., et al., *Do Proton Pump Inhibitors decrease calcium absorption?*, J. BONE  
 18 MINER. RES. 2010; 25 (12): 2510-19.

19 <sup>4</sup> Wright M.J., et al., *Inhibiting gastric acid production does not affect intestinal calcium*  
 20 *absorption in young, healthy individuals: a randomized, crossover, controlled clinical*  
 21 *trial*, J. BONE MINER. RES. 2010; 25 (10): 2205-11.

22 <sup>5</sup> Plaintiffs confuse two concepts. (Resp. at p. 19.) It is accepted that decreased calcium  
 23 uptake can lead to osteoporosis. That is not at issue here. What **is** at issue is whether  
 24 Nexium® can decrease calcium uptake. Plaintiffs assert incorrectly that "Defendants'  
 25 experts offer no opinion or evidence to refute that Nexium® or any other PPI can cause a  
 26 decrease in calcium uptake." (*Id.*) As discussed herein, Defendants' experts' reports  
 27 disclose and discuss *Wright* and *Hansen* both which disprove the proposition that  
 28 Nexium® causes decreased calcium uptake (which then could cause osteoporosis).

<sup>6</sup> Ensrud K.E., *Low Fractional Calcium Absorption Increases the Risk for Hip Fracture*  
*in Women with Low Calcium Intake*, ANNALS INT'L MED. 2000; 132 (5): 345-53.

1        Regardless, as discussed above, Dr. Bal's opinion that Nexium® reduces  
 2 calcium intake – is not his only speculated method by which he believes Nexium®  
 3 use may be "causally associated" with OP. Rather, Dr. Bal **also** states that  
 4 Nexium® (like Fosamax®) has a direct effect on osteoclasts which, if true, would  
 5 protect bone by preserving calcium in bone. Thus, his opinion that reduced bone  
 6 turnover from Nexium® use is bad for bone is antithetical to his *Fosamax* opinion.

7            **C.    Plaintiffs' Response Confirms That Dr. Bal Is Testifying As To An**  
 8            **"Association" Only. As Such, His Testimony Is Unhelpful.**

9        Plaintiffs affirm that Dr. Bal's opinion is that Nexium® is "causally  
 10 associated" with OP – not that Nexium® **causes** OP. (Resp. at pp. 1, 12.) This is  
 11 consistent with his expert report and his necessary concession that his report  
 12 contained a full and complete statement of all of his opinions in this case.  
 13 Accordingly, his "association"-only opinion is "unhelpful."

14        Plaintiffs do not argue against the established proposition that "association"  
 15 does not equal causation. (Master Dkt. 255, p. 17; *see also generally* Resp.) In  
 16 fact, *In re TMI Litig.*, cited by Plaintiffs, reiterates that "Association is a term of art  
 17 in epidemiology. It is defined as '[t]he degree of statistical dependence between  
 18 two or more events or variables. . . Association does not necessarily imply a causal  
 19 relationship.'" 193 F.3d 613, 710 n.159 (3d Cir. 1999). Rather, they argue that  
 20 causation may be "impl[ied]" from association studies and that such studies "add[]  
 21 weight." (Resp. at p. 13, lines 11, 15.) However, they admit that no inference can  
 22 be drawn from associational studies alone. Rather, association studies must be  
 23 "[c]ombined with accepted mechanisms of action, and corroborating evidence from  
 24 other scientific studies, when combined with other supportive data." (*Id.*)<sup>7</sup> And,

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25  
 26 <sup>7</sup> Plaintiffs assert that Defendants' experts require "black and white," "gold standard"

1 Plaintiffs do not have any such corroborating evidence. Plaintiffs do not offer  
 2 "accepted" mechanisms of action supported by any studies. **Exh. A** (Bal Dep.  
 3 118:24-119:5.) They rely upon no other clinical studies or supportive data.  
 4 Accordingly, Dr. Bal's association-only opinion is not "helpful" to the only issue  
 5 presented here – whether Nexium® can cause OP.

6 Plaintiffs' Response highlights this dichotomy between evidence of  
 7 association versus causation when it discusses a study conducted by Targownik in  
 8 2008. (Resp. at p. 3.) Plaintiffs assert that this association study establishes that  
 9 Nexium® use increases the risk of hip fracture. **Dr. Targownik submitted an**  
 10 **expert report in this case that undermines Plaintiffs' lay interpretation of her**  
 11 **work.**<sup>8</sup> She conducted the study, and she does not believe that the scientific  
 12 evidence (including her multiple studies) supports that Nexium® use causes OP -  
 13 even though her 2008 study found an **association** between the two events. (Master  
 14 Dkt. 255-4, Targownik Rpt.) As Dr. Targownik explains: receiving the morning  
 15 newspaper is highly associated with the sun rising. However, the newspaper  
 16 delivery does not cause the sun to rise nor the converse. (*Id.* at p. 3.) An  
 17 association is "nothing more than a temporal association between variables." **Exh.**  
 18 **A** (Bal Dep. 30:23-25.) "When you see an association, you cannot or should not  
 19 jump to a cause and effect relationship. That requires more data." (*Id.* at 32:8-12.)

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 22  
 23 evidence before causation can be inferred. (Resp. at p. 16.) However, their cites to Dr.  
 24 Bal do not support this assertion. Moreover, Dr. Targownik's report explains that criteria  
 25 are employed by epidemiologists "to determine whether an observational association is  
 26 likely to represent causation . . . ." (Master Dkt. 255-4, Targownik Rpt., p. 4.)

27  
 28 <sup>8</sup> Plaintiffs' attorneys in the Response, not their purported expert Dr. Bal, make this  
 assertion about Dr. Targownik's work. It is unquestionably an inadmissible lay opinion.

**D. Plaintiffs' Response Fails To Address The Fundamental Underlying Analytical Gaps Which Render Dr. Bal's Opinion Unreliable.**

None of the arguments set forth in Plaintiffs' Response demonstrate that Dr. Bal's opinion in this case should be deemed reliable under Rule 702 and *Daubert*.<sup>9</sup> To the contrary, there is too large of an analytical gap between the items he relies upon and the opinion he reaches.<sup>10</sup> In sum, the association studies he relies upon:

- do not agree that causation has been established,<sup>11</sup>
- are not on Nexium® – the only medication Dr. Bal implicates in his opinions, and
- at best speculate with regard to possible mechanisms of action.

Dr. Bal's opinion cannot reliably extend to a conclusion where the literature upon which he relies has not reached such a conclusion and he has done no independent research. Law is meant to lag science, not allow speculation to stand as science.

First, Plaintiffs assert that Dr. Bal should be able to rely upon studies that never studied Nexium®, or studied it only as part of a class of medications. (Resp. at pp. 11-12.) Whether or not it would be scientifically appropriate,<sup>12</sup> Dr. Bal has

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<sup>9</sup> As proffered "scientific" evidence, Dr. Bal's opinion is subject to the *Daubert* factors as discussed in Defendants' opening brief. *Cf. United States v. Hankey*, 203 F.3d 1160, 1168 (9th Cir. 2000) (courts have "broad discretion" in reviewing proffered nonscientific, *i.e.*, *Kumho* expert evidence).

<sup>10</sup> Additionally, as discussed in the opening brief, Dr. Bal's opinion is driven by litigation. (Master Dkt. 255, pp. 18-19.) Plaintiffs do not address this argument. In the interest of brevity, Defendants therefore incorporate by reference their prior brief as it relates to this issue.

<sup>11</sup> Plaintiffs in their Response do not contest this point.

<sup>12</sup> Plaintiffs argue that because the FDA issued classwide PPI labeling for bone fracture, it would be reliable for Dr. Bal to rely on studies conducted on other PPIs. Setting aside that Dr. Bal precludes this methodology by contending there is no class-wide effect, the

1 decided that his opinion is not generalizable to other PPIs and, thus, he **only** opines  
 2 that Nexium® is causally associated with OP. **Exh. A** (Bal Dep. 78:11-14, 121:23-  
 3 122:25.) Relying on studies of other medications, therefore, admittedly is not  
 4 supportive or reliable because it would be inconsistent with his opinion that it is  
 5 not a class-wide effect. *Cf. Tucker*, 701 F. Supp. 2d at 1056 (allowing expert to  
 6 rely upon studies of a class of medications, but no contention that expert himself  
 7 did not know the medications to be sufficiently similar to treat as a class).

8 Next, Plaintiffs contend that because Dr. Bal necessarily limited his opinions  
 9 to only certain fracture sites, it therefore must be reliable. (Resp. at p. 16.)  
 10 Plaintiffs provide no support for the point that a narrow rather than broad opinion  
 11 is necessarily more reliable. Regardless, Dr. Bal's posited opinion is that Nexium®  
 12 causes osteoporosis and only "osteoporotic" fractures. However, the studies he  
 13 relies upon did not find that PPIs were associated with a reduction in bone mineral  
 14 density (BMD), *i.e.*, osteoporosis. **Exh. A** (Bal Dep. 148:15-149:9.)

15 Further, Plaintiffs contend that Dr. Bal implicitly applied the Bradford Hill  
 16 criteria and therefore his opinion is more reliable. (Resp. at p. 17.) Nothing in Dr.  
 17 Bal's report or deposition discloses that Dr. Bal used this or any other recognized  
 18 methodology to assist in determining whether an observed association is causal.  
 19 Rather, Plaintiffs in their Response **argue** that what they read about Dr. Bal's  
 20 opinions seem to comport with Plaintiffs' interpretation of this epidemiologic  
 21

22 FDA label and communications regarding the label are not, in themselves, any evidence  
 23 of causation. Federal regulations make clear that a "causal relationship need not have  
 24 been proved" for a warning to issue. 21 C.F.R. § 201.57(e). Furthermore, the FDA  
 25 language at issue does not assert or imply an established causation ("The available data . .  
 26 . suggest a **possible** increased risk of fractures of the hip, wrist, and spine. . . . [T]here is  
 uncertainty about the magnitude of this risk."). (Master Dkt. 288-3, Exh. J.) (emphasis  
 added).

1 criteria. Regardless of whether Dr. Bal would be competent to apply the criteria  
 2 (which Defendants deny), Plaintiffs and their counsel undoubtedly are not.  
 3 Moreover, the cites to Dr. Bal's deposition transcript do not relate to the Bradford  
 4 Hill criteria that Plaintiffs cite: temporality, strength of association, alternative  
 5 explanations, consistency or biologic plausibility. (*See* Resp., p. 17, cited Bal  
 6 Dep.)<sup>13</sup> The only disclosed expert to engage in this analysis was the  
 7 gastroepidemiologist Dr. Targownik. (Master Dkt. 255-4, Targownik Rpt., pp. 4-  
 8 9.) She was explicit in use of the methodology and concluded that application of  
 9 the criteria did not imply a causal relationship. (*Id.* at p. 9.)

10 Finally, Plaintiffs argue that lack of an "established" mechanism of action  
 11 and the presence of Defendants' own experts cannot *ipso facto* make their expert  
 12 inadmissible. Plaintiffs misunderstand the significance of these issues. As to the  
 13 lack of accepted mechanism of action, such missing evidence is "significant" if not  
 14 dispositive to a *Daubert* analysis as to whether the expert's opinion is reliable.  
 15 *Schudel v. Gen. Elec. Co.*, 120 F.3d 991, 997 (9th Cir. 1997). Additionally, as  
 16 addressed above, Plaintiffs contend that causation may be "implied" from the items  
 17 Dr. Bal relies upon which include his opinions regarding a "plausible", but not  
 18 "established," mechanism of action. However, *Tucker, supra*, does not support  
 19 reliance upon a merely "plausible" mechanism of action. Rather, the mechanism  
 20 must be "accepted," a difference that Dr. Bal appears to understand. **Exh. A** (Bal  
 21 Dep. 106:25-107:10) (stating that he did not recall "any accepted or recognized"

22  
 23  
 24 <sup>13</sup> For example, Bal Dep. 73:8-13 (which was cited for alternative explanations,  
 25 consistency with scientific knowledge and biologic plausibility) states nothing more than  
 26 how Nexium® works: Q. Do you know the clinical pharmacology is by which proton  
 pump inhibitors work? A. Yeah. They decrease the secretion of acids and quite  
 dramatically in the stomach. **Exh. A** (Bal Dep. 73:8-13.)



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PHARMACEUTICALS LP, ASTRAZENECA  
LP, and MCKESSON CORPORATION

**CERTIFICATE OF SERVICE**

I, Katherine A. Winchester, declare:

I am a citizen of the United States and employed in Indianapolis, Indiana. I am over the age of eighteen years and not a party to the within-entitled action. My business address is One American Square, Suite 2900, Indianapolis, Indiana 46282.

On May 22, 2014, I served a copy of the within document(s):

**DEFENDANTS' REPLY IN FURTHER SUPPORT OF MOTION TO  
EXCLUDE PLAINTIFFS' GENERAL CAUSATION EXPERT  
B. SONNY BAL, M.D., J.D., M.B.A.**

On all parties in this action by causing a true copy thereof to be distributed as follows:

☒ BY ELECTRONIC SERVICE VIA PACER: I caused such documents to be transmitted via electronic mail to the stated parties via an electronic service known as PACER.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Executed on May 22, 2014, at Indianapolis, Indiana.

/s/ Katherine A. Winchester  
KATHERINE A. WINCHESTER